

February 10, 2023

Vascular Solutions, Inc.  
c/o Lisa Gallatin, RAC  
Senior Regulatory Affairs Associate  
6464 Sycamore Court  
Minneapolis, Minnesota 55369

Re: K083190  
Trade/Device Name: D-Stat® Dry Wrap Hemostatic Bandage  
Regulatory Class: Unclassified  
Product Code: QSX

Dear Lisa Gallatin:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 12, 2008. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSX.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, [Julie.Morabito@fda.hhs.gov](mailto:Julie.Morabito@fda.hhs.gov).

Sincerely,

**Julie A. Morabito -S**

Julie Morabito, Ph.D.  
Assistant Director  
DHT4B: Division of Infection Control  
and Plastic Surgery Devices  
OHT4: Office of Surgical  
and Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Vascular Solutions, Inc.  
% Ms. Lisa Gallatin, RAC  
Senior Regulatory Affairs Associate  
6464 Sycamore Court  
Minneapolis, Minnesota 55369

NOV 12 2008

Re: K083190

Trade/Device Name: D-Stat<sup>®</sup> Dry Wrap Hemostatic Bandage  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: October 28, 2008  
Received: October 29, 2008

Dear Ms. Gallatin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

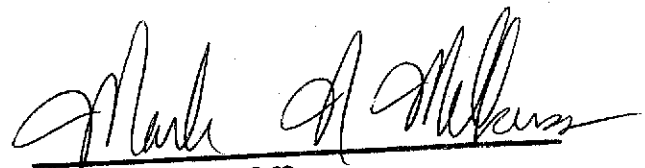
Enclosure

## INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K083190

Device Name: D-Stat® Dry Wrap Hemostatic Bandage

**Indications for Use:** The D-Stat® Dry Wrap hemostatic bandage is applied topically as an adjunct to manual compression and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.



(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K083190

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page \_\_\_\_ of \_\_\_\_

**510(K) SUMMARY**  
[As required by 21 CFR 807.92)]

**1. Submitter's Name / Contact Person**

**NOV 12 2008**

**Manufacturer**

Vascular Solutions, Inc.  
6464 Sycamore Court  
Minneapolis, MN 55369 USA  
Tel: 763.656.4300  
Fax: 763.656.4250

**Contact Person**

Lisa Gallatin, RAC  
Sr. Regulatory Affairs Associate  
Tel: 763.656.4399 (Direct)  
Fax: 763.656.4250  
lgallatin@vascularsolutions.com

**2. General Information**

**Trade Name**

D-Stat® Dry Wrap Hemostatic Bandage

**Common / Usual Name**

Topical Hemostat

**Classification Name**

Dressing, Wound, Drug

**Identification of Equivalent Devices**

Thrombix™ Patch Thrombin Hemostasis Patch (K072117)

D-Stat® Dry Clear Hemostatic Bandage (K073264)

**3. Intended Use**

The D-Stat® Dry Wrap is applied topically as an adjunct to manual compression and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.

**4. Device Description**

The D-Stat® Dry Wrap Hemostatic Bandage consists of a lyophilized pad containing bovine-derived thrombin as an aid to hemostasis (King Pharmaceuticals license number 0977), sodium carboxymethylcellulose (CMC), and calcium chloride. The sterile device is sold in a foil pouch and is ready to use. The end user removes the D-Stat Dry Wrap from the pouch and applies the device to the bleeding site. Included is a transparent sterile bandage attached to the primary packaging to apply over the hemostatic pad. The pad has a slit approximately half the length of the pad to allow for the wrapping of the pad around vascular access catheters, like PICC (peripherally inserted central catheter) lines.

The D-Stat® Dry Wrap is applied directly over the source of bleeding, creating a physical barrier to blood flow through the application of adjunctive manual compression. The lyophilized components (thrombin, CMC, and calcium chloride) establish an environment in which a natural blood clot can build and form a physical carrier to bleeding.

**5. Statement of Equivalence**

The D-Stat® Dry Wrap is substantially equivalent to the Vascular Solutions, Inc. Thrombix™ Patch Thrombin Hemostasis Patch (K072117) and D-Stat® Dry Clear Hemostatic Bandage (K073264) products. The D-Stat® Dry Wrap only differs from this predicates in that it has a lengthwise slit cut in the lyophilized pad to allow placement of the pad around existing access lines.

**6. Conclusion**

The D-Stat® Dry Wrap is substantially equivalent to the currently marketed Thrombix™ Patch Thrombin Hemostasis Patch and D-Stat® Dry Clear Hemostatic Bandage products based on a comparison of the indications for use and technological characteristics of the device.